

Application No.: 10/691,849
Amendment and Response dated November 20, 2006
Reply to Office Action of August 23, 2006
Docket No.: 760-234
Page 2

Amendments to the Specification:

Immediately prior to paragraph [0001], please amend the section description, as follows:

~~BACKGROUND OF THE INVENTION~~ FIELD OF THE INVENTION

Immediately prior to paragraph [0002], please add the section description, as follows:

BACKGROUND OF THE INVENTION

Please amend paragraph [0010], as follows:

[0010] In one aspect, the present invention provides a method of reducing blood flow into a perigraft space between an endovascular graft and an artery wall. The method comprises accessing the perigraft space with a delivery device and delivering an embolic material into the perigraft space with the delivery device. The embolic material may comprise polyethylene glycol diacrylate, ~~pentaerythritol~~ pentaerythritol tetra 3(mercaptopropionate), and a buffer.

Please amend paragraph [0012], as follows:

[0012] The polyethylene glycol diacrylate typically has a molecular weight between about 700 and about 800 and may be provided in a proportion ranging from about 50 to about 55 weight percent. The ~~pentaerythritol~~ pentaerythritol tetra 3(mercaptopropionate) may be provided in a proportion ranging from about 0.31 to about 0.53 times weight percent of the polyethylene glycol diacrylate present. If desired saline or other inert biocompatible materials may be added to the three component embolic material.

Please amend paragraph [0019], as follows:

[0019] In another aspect, embodiments of the present invention provide systems for delivering an embolic material into a perigraft space. The systems may include a delivery device configured to access the perigraft space and configured to deliver an embolic material to the perigraft space. An occlusion assembly is configured to substantially reduce a blood flow through the endovascular graft during delivery of the embolic material. The embolic material may comprise polyethylene glycol diacrylate, ~~pentaerythritol~~ pentaerythritol tetra 3(mercaptopropionate), and a buffer.

Please amend paragraph [0021], as follows:

[0021] The embolic material may be radiopaque. The buffer may be HEPES or glycylglycine. The glycylglycine may be provided in a proportion ranging from about 5 to about 40 weight percent. The polyethylene glycol diacrylate may have a molecular weight between 700 and 800 and maybe provided in a proportion ranging from about 50 to about 55 weight percent. The ~~pentaerythritol~~ pentaerythritol tetra 3(mercaptopropionate) may be in a proportion ranging from about 0.31 to about 0.53 times the weight percent of the polyethylene glycol diacrylate present.

Please amend paragraph [0023], as follows:

[0023] In a further aspect, the present invention provides a kit for depositing an embolic material in a perigraft space between an endovascular graft and an artery wall. The kit may comprise a delivery device configured to access the perigraft space and an embolic material comprising polyethylene glycol diacrylate, ~~pentaerythritol~~ pentaerythritol tetra 3(mercaptopropionate), and a buffer.

Application No.: 10/691,849
Amendment and Response dated November 20, 2006
Reply to Office Action of August 23, 2006
Docket No.: 760-234
Page 4

Please amend paragraph [0025], as follows:

[0025] The buffer may comprise a glycylglycine buffer, and may be present in a proportion ranging from about 5 to about 40 weight percent. The polyethylene glycol diacrylate typically comprises a molecular weight between 700 and 800 and may be present in a proportion ranging from about 50 to about 55 weight percent. The ~~pentaerythritol~~ pentaerythritol tetra 3(mercaptopropionate) may be present in a proportion ranging from about 0.31 to about 0.53 times the weight percent of the polyethylene glycol diacrylate present.

Please amend paragraph [0058], as follows:

[0058] One class of suitable materials for embolization is the family of Michael addition polymers formed by reaction of an acrylate monomer and a multi-thiol. These materials can be delivered in liquid or semi-liquid form, and thereafter crosslink *in situ* to form a solid polymer gel. Details of the Michael addition polymer class of compositions suitable for use as an embolic material are described in U.S. Patent Application Serial No. 09/496,231 to Hubbell et al., filed February 1, 2000 and entitled "Biomaterials Formed by Nucleophilic Addition Reaction to Conjugated Unsaturated Groups" and U.S. Patent Application Serial No. 09/586,937 to Hubbell et al., filed June 2, 2000, now U.S. Patent No. 6,958,212, and entitled "Conjugate Addition Reactions for the Controlled Delivery of Pharmaceutically Active Compounds". The entirety of each of these patent applications is hereby incorporated herein by reference.

Please amend paragraph [0059], as follows:

[0059] One Michael addition material suitable for endoleak management applications is a polymer formed by mixing polyethylene glycol diacrylate (PEGDA) with ~~pentaerythritol~~ pentaerythritol tetra (3-mercaptopropionate) (QT). A buffer such as glycylglycine or other

suitable compound may be added to adjust the solidification time and/or the viscosity of the liquid components prior to curing as described below in greater detail.

Please amend paragraph [0062], as follows:

[0062] Variations of these components and other formulations as described in copending U.S. Patent Application Serial Nos. 09/496,231 and 09/586,937 (now U.S. Patent No. 6,958,212, both to Hubbell et al., may be used as appropriate. The entirety of each of these patent applications is hereby incorporated herein by reference. In addition, PEGDA having a molecular weight ranging from about 350 to about 850 may be useful; PEGDA having a molecular weight ranging from about 440 to about 750 are also particularly useful.

Please amend paragraph [0071], as follows:

[0071] Cure times may be tailored by adjusting the formulations, mixing protocol, and other variables according to the requirements of the clinical setting.[[.]]

Please amend paragraph [0075], as follows:

[0075] FIG. 5 illustrates a system 30 for managing endoleaks according to an embodiment of the present invention. System 30 includes a delivery device 32 for accessing the perigraft space. Delivery device 32 may include one or more of a catheter 18, a syringe and needle 18', or other conventional devices that may be used to access a perigraft space. System 30 also includes an embolic material 34 that is deliverable by delivery device 18 into the perigraft space. The embolic material may be a three-component mixture, such as a mixture of polyethylene glycol diacrylate, ~~pentaerythritol~~ pentaerythritol tetra 3(mercaptopropionate), and a buffer. In the illustrated embodiment, each of the separate components of the embolic material are stored in separate containers 35, 37, 39 and are mixed together just prior to delivery. As

can be appreciated, embolic material 34 may be composed of any of the other materials described herein.

Please amend paragraph [0097], as follows:

[0097] The embolic material may be delivered into the perigraft space via the embolic material delivery channels or lumen 80 in a variety of ways. For instance, the embolic material may be delivered to channels 80 via an injection port 84 (which may be similar to (FIG. 11) or the same as (FIG. 10) injection port 63). The embolic material may travel through channel 80 and exit channel 80 into the perigraft space through one or more abluminal apertures or openings 82 in the channels. Some useful aperture configurations are shown in FIGS. 10-12. The examples show that the one or more apertures 82 are disposed (1) near the proximal cuff 56 of the graft, (2) in the mid-graft region (and preferably configured to be oriented towards the aneurysm sac AS upon deployment to facilitate filling of the perigraft space), and/or (3) in a region of the graft near the distal cuff 57.

Please amend paragraph [0101], as follows:

[0101] Various embodiments of grafts and stent-grafts, methods of manufacturing the grafts, and methods of delivering the grafts are described in co-pending and commonly owned U.S. Patent Application Ser. No. 10/029,557, which published as U.S. Patent Application Publication No. 2003/0116260 A1, entitled "Method and Apparatus for Manufacturing an Endovascular Graft Section", U.S. Patent Application Ser. No. 10/029,570, now U.S. Patent No. 6,776,604, entitled "Method and Apparatus for Shape Forming Endovascular Graft Material", U.S. Patent Application Ser. No. 10/029,584, now U.S. Patent No. 7,090,693, entitled "Endovascular Graft Joint and Method of Manufacture", by Chobotov et al., all of which were filed December 20, 2001, U.S. Patent Application Ser. No. 10/327,711, which published as U.S. Patent Application Publication No. 2003/0125797 A1, entitled "Advanced

Application No.: 10/691,849
Amendment and Response dated November 20, 2006
Reply to Office Action of August 23, 2006
Docket No.: 760-234
Page 7

Endovascular Graft”, by Chobotov et al., filed December 20, 2002, PCT Application No. PCT/US02/40997, which published as WO/2003/053495 A2, entitled “Method and Apparatus for Manufacturing an Endovascular Graft,” by Chobotov et al., filed December 20, 2002, U.S. Patent Application Ser. No. 09/774,733, now U.S. Patent No. 6,602,280, entitled “Delivery System and Method for Expandable Intracorporeal Device,” by Chobotov et al, filed January 31, 2002 and U.S. Patent Application Ser. No. 10/122,474, which published as U.S. Patent Application Publication No. 2003/00045460 A1, entitled “Delivery System and Method for Bifurcated Endovascular Graft,” by Chobotov et al., filed April 11, 2002, the entirety of each of which are incorporated herein by reference. Other embodiments of devices incorporating features and methods described herein are disclosed in U.S. Patent No. 6,395,019 (May 28, 2002) to Chobotov, the entirety of which is incorporated herein by reference.

Application No.: 10/691,849

Amendment and Response dated November 20, 2006

Reply to Office Action of August 23, 2006

Docket No.: 760-234

Page 8

Please amend the abstract on page 28, as follows:

The present invention provides methods and compositions for managing endoleaks in a perigraft space around an endovascular graft. In one embodiment, a blood flow through the endovascular graft is temporarily reduced and an embolic material is delivered into the perigraft space while the blood flow through the endovascular graft is reduced. The embolic material may comprise polyethylene glycol diacrylate, ~~pentaerythritol~~ pentaerythritol tetra 3(mercaptopropionate), and a buffer.